REMARKS

Claims 4, 42, and 65-112 are pending and under examination. Applicants have hereinabove canceled claims 111 and 112 without prejudice or disclaimer to applicants' right to pursue the subject matter of these claims in the future. In addition, applicants have hereinabove amended claims 4, and 85-96. Applicants maintain the amendments to the claims raise no issue of new matter. Support for the amendments to claim 4 can be found in the specification as originally filed at, *inter alia*, page 23, line 19 to page 24, line 13. Claims 85-96 have been amended merely to correct antecedent basis. Accordingly, applicants respectfully request that this Amendment be entered. After entry of this Amendment, claims 4, 42, and 65-110 will be pending and under examination.

Claims Rejected Under 35 U.S.C. §112, First Paragraph

In the December 16, 2003 Office Action, the Examiner stated that claims 4, 42 and 65-112 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner further stated that applicants' invention is described to a method of determining whether a compound enhanced formation of a complex between a p66 subunit and a p51 subunit polypeptides of HIV-1 reverse transcriptase. The Examiner also stated that although applicants may have constructed a yeast cell comprising the appropriate plasmids expressing fusion proteins to detect a compound that may enhance formation of the complex, applicants have not isolated any compound that indeed enhances the formation of the complex, thus

showing that such a method actually works, and, lacking any evidence to the contrary, applicants have not enabled the invention

In response, applicants respectfully traverse the Examiner's rejection. Applicants note that, contrary to the Examiner's position, the specification discloses compounds that enhance the formation of a complex between a p66 subunit polypeptide of HIV-1 reverse transcriptase and a p51 subunit polypeptide of HIV-1 reverse transcriptase as recited in the claimed method. Specifically, applicants note that efavirenz, the carboxanilide UC781, and the quinoxaline HBY 097 all enhanced complex formation, see the experimental description at page 107, lines 4-7; page 109, lines 3-6; page 111, lines 5 to 12, and the results and discussion at page 112, lines 19 to 13; and page 119, lines 28 to page 120, line 2. Accordingly, applicants maintain that the claimed subject matter is fully enabled by the specification, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

The Examiner stated that claims 98-110 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is not nearly connected, to make and/or use the invention. The Examiner stated that applicants have not shown any convincing evidence that the invention would actually work in a subject, i.e., *in vivo*, and have not shown that the method would work *in vitro*.

In response, applicants respectfully traverse the Examiner's rejection. Applicants note that the specification discloses compounds that enhance the formation of a complex between a p66

subunit polypeptide of HIV-1 reverse transcriptase and a p51 subunit polypeptide of HIV-1 reverse transcriptase as recited in the claimed method, and applicants have hereinabove pointed out such support in the specification. In addition, applicants note that the specification discloses at page 120, lines 16-29, various NNRTIs which are effective in the claimed method are also clinically efficacious, e.g. efavirenz. Accordingly, applicants maintain that the specification discloses a reasonable correlation between *in vitro* utility and *in vivo* activity, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claims Rejected Under 35 U.S.C. §112, Second Paragraph

The Examiner stated that claims 111 and 112 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim subject matter which applicant regards as the invention.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove canceled claims 111 and 112 without prejudice or disclaimer to applicants' right to pursue the subject matter of these claims in the future.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. § 1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit**

A) and attached hereto as **Exhibits 1-4**:

1. U.S. Patent Application No. 10/006/626, filed December 6, 2001; (Exhibit 1)

2. U.S. Patent Application No. 10/670/652, filed September 25, 2003; (Exhibit 2)

3. Tachedjian, G. et al. (2000) "Analysis of Mutations and Suppressors Affecting Interactions Between the Subunits of the HIV Type-1 Reverse Transcriptase" *PNAS* 97(12):6334-6339; (Exhibit 3) and

4. Boyer, P. et al. (1994) "Subunit Specificity of Mutations that Confer Resistance to Nonnucleoside Inhibitors in Human Immunodeficiency Virus Type-1 Reverse Transcriptase" *Antimicrobial Agents and Chemotherapy*, 38(9):1909-1914. (Exhibit 4).

This Supplemental Information Disclosure Statement supplements the Information Disclosure Statement filed by applicants January 23, 2002 in connection with the above-identified application. References 3-4 were first cited in a Supplementary Partial European Search report issued February 25, 2004 in connection with related European Application No. 01939917.9-2402. A copy of the Supplementary Partial European Search Report is attached hereto as **Exhibit B**.

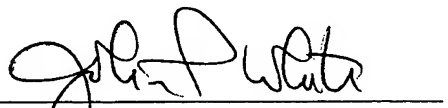
This Supplemental Information Disclosure Statement is submitted under 37 C.F.R. §1.97(c)(2). Accordingly, a check including the amount of ONE HUNDRED AND EIGHTY DOLLARS ($180.00) is enclosed

herewith to cover the fee set forth in 37 C.F.R. §1.17(p).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, apart from the enclosed total fee of $600.00, including $180.00 fee for filing an Information Disclosure Statement and $420.00 fee for a two month extension of time, is deemed necessary in connection with the filing of this Amendment. If any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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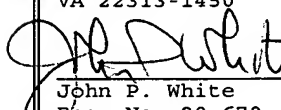
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



5/17/04

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Date